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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,523	04/19/2004	Malcolm J. Fraser JR.	UNND-0061-4	2881
22506	7590	02/10/2005	EXAMINER	
JAGTIANI + GUTTAG 10363-A DEMOCRACY LANE FAIRFAX, VA 22030			DUNSTON, JENNIFER ANN	
			ART UNIT	PAPER NUMBER
			1636	
DATE MAILED: 02/10/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/826,523

Applicant(s)

FRASER ET AL.

Examiner

Jennifer Dunston

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9, 11 and 16 is/are allowed.
- 6) ☒ Claim(s) 1-8, 10, 12-15 and 17-19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/19/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claims 1-19 are pending in the instant application.

Information Disclosure Statement

Receipt of an information disclosure statement, filed on 4/19/2004, is acknowledged. The signed and initialed PTO 1449 has been mailed with this action. The non-patent literature references were not considered because copies were not provided.

Drawings

The drawings are objected to because Figure 26 does not contain the reference character "c" as described in the brief description of the drawing. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the

Art Unit: 1636

examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities: the first paragraph of the specification contains a blank in reference to the application number of the US Patent Application entitled "Methods and Compositions for Transposition Using Minimal Segments of the Eukaryotic Transformation Vector *PiggyBac*." The missing application number has not been provided on the oath or declaration and thus the claim for priority to said application has not been perfected.

Appropriate correction is required.

Claim Objections

Claims 1 and 14-17 are objected to because of the following informalities: the term *piggyBac* appears to be misspelled in all occurrences. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-8 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims encompass a DNA molecule that reads on the *piggyBac* molecule, also known as the IFP2 transposon (see the rejection under 35 USC 102 below). The

Art Unit: 1636

piggyBAC transposon is found in nature in the genome of the cabbage looper moth, *Trichoplusia ni*. It would be remedial to insert the term "isolated" in connection with the DNA to indicate that the DNA is a product not found in nature.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8, 14, 15, 18 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in that the metes and bounds of the term "said region" in line 4 of the claim are unclear. It is not clear if the term refers to the 3' terminal region or the 5' terminal region recited in the body of the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10, 12, 13 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 10 is drawn to a genetic cartridge designated ITR1.1k. Claims 12 and 13 are drawn to vectors designated pXL-BacII-ECFP and pBSII-ITR1.1k-ECFP, respectively, as shown in Figure 24. Claim 17 encompasses the step of obtaining the ITR1.1k cartridge.

The application discloses the abovementioned cartridge and vectors that are encompassed by the definitions for **biological material** set forth in 37 C.F.R. § 1.801. Because it is apparent that this biological material is essential for practicing the claimed invention, it must be obtainable by a reproducible method set forth in the specification or otherwise be known and readily available to the public as detailed in 37 C.F.R. §§ 1.801 through 1.809.

It is unclear whether this biological material is known and readily available to the public or that the written instructions are sufficient to reproducibly construct this biological material from starting materials known and readily available to the public. The specification does not appear to describe the nucleic acid sequences of the cartridge or vectors. Accordingly, availability of such biological material is deemed necessary to satisfy the enablement provisions of 35 U.S.C. § 112. If this biological material is not obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the biological material. In order for a deposit to meet all criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants or assignee must provide assurance of compliance with provisions of 37 C.F.R. §§ 1.801-1.809, in the form of a declaration or applicant's representative must provide a statement. The content of such a declaration or statement is suggested by the enclosed attachment. Because such deposit will not have been made prior to the effective filing date of the instant application, applicant is required to submit a verified statement from a person in a position to corroborate the fact, which states that the biological material which has been deposited is the biological material specifically

Art Unit: 1636

identified in the application as filed (37 C.F.R. § 1.804). Such a statement need not be verified if the person is an agent or attorney registered to practice before the Office. Applicant is also reminded that the specification must contain reference to the deposit, including deposit (accession) number, date of deposit, name and address of the depository, and the complete taxonomic description. A statement that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon granting of a patent is also required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 15, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Cary et al (Virology, Vol. 172, No. 1, pages 156-169, 1989; see the entire reference).

Cary et al teach a DNA molecule comprising the entire *piggyBac* (i.e. IFP2) molecule, including a right terminal repeat, a right internal repeat, a left internal repeat and a left terminal repeat (e.g. Figures 2 and 5). The total length of the *piggyBac* molecule taught by Cary et al is 2475 nucleotides (e.g. Figure 5). Therefore, the *piggyBac* molecule taught by Cary et al comprises at least 276 consecutive nucleotide base pairs of the 3' terminal region beginning at the 3' terminal base pair and at least 172 consecutive nucleotide base pairs of the 5' terminal region beginning at the 5' terminal base pair.

Regarding claims 3-5 and 6-8, it is noted that the specification defines the term “spacer” as sequences “separating the 5’ and 3’ (respectively) terminal repeat and internal repeat sequences of the *piggyBac* transposon.” Carey et al teach that the sequence between the right terminal repeat (5’ terminal repeat) and left internal repeat (3’ internal repeat) is greater than 55 base pairs and thus is a spacer of at least 55 base pairs between the 5’ and 3’ (respectively) terminal repeat and internal repeat sequences of the *piggyBac* transposon (e.g. Figure 5).

Cary et al teach a method of inserting the *piggyBac* molecule described above into a pUC8 recipient plasmid (e.g. page 157, right column). Further, the *piggyBac* molecule inserted into pUC8 comprises the genes encoding orf1 and orf2 of the *piggyBac* transposon (e.g. Figure 5). Cary et al teach that the resulting plasmid clone, comprising the *piggyBac* molecule and further comprising the pUC8 plasmid backbone, is capable of being transferred to a cell such as *E. coli* strain 71-18 (e.g. page 157, right column, last paragraph).

Relevant Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 6,733,914 B1 (Handler et al) Piggybac transformation system.

Elick et al. PCR analysis of insertion site specificity, transcription, and structural uniformity of the Lepidopteran transposable element IFP2 in the TN-368 cell genome. *Genetica*. 1996 Mar;97(2):127-39.

Elick et al. Excision of the piggyBac transposable element in vitro is a precise event that is enhanced by the expression of its encoded transposase. *Genetica*. 1996 Jul;98(1):33-41.

Fraser et al. Assay for movement of Lepidopteran transposon IFP2 in insect cells using a baculovirus genome as a target DNA. Virology. 1995 Aug 20;211(2):397-407.

Fraser et al. Precise excision of TTAA-specific lepidopteran transposons piggyBac (IFP2) and tagalong (TFP3) from the baculovirus genome in cell lines from two species of Lepidoptera. Insect Mol Biol. 1996 May;5(2):141-51.

Li et al. The minimum internal and external sequence requirements for transposition of the eukaryotic transformation vector piggyBac. Mol Genet Genomics. 2001 Oct;266(2):190-8.

Conclusion

Claims 9, 11 and 16 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR, <http://pair-direct.uspto.gov>) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to


Art Unit: 1636

midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jennifer Dunston
Examiner
Art Unit 1636

jad


TERRY MCKELVEY
PRIMARY EXAMINER